Remarks

The Examiner has rejected all pending claims. Applicants respectfully traverse the Examiner's rejection.

Claim Rejections – 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-31 under 35 U.S.C. § 103(a) as being unpatentable over DE 201055990 U1 to Stryker Leibinger ("Stryker") in view of U.S. Patent No. 5,954,747 to Clark ("Clark"). It is the Examiner's position that Stryker discloses the claimed invention except for a guide sleeve comprising a single point. Stryker, as admitted by the Examiner, comprises multiple points projecting from its face. The Examiner has further stated that Clark discloses a single point projecting from its distal end. The Examiner concludes that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Stryker Leibinger having at least a single point projecting distally, as this construction would be beneficial in contacting the bone surface for optimum positioning of the suture anchor."

The Applicants respectfully traverse this rejection because the Examiner has not provided any valid or plausible reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. Stryker and Clark teach away from the combination suggested by the Examiner and the claimed invention. Stryker teaches that it is imperative to provide at least four teeth to hold and maintain two bone pieces together and avoid a lateral deviation or lateral movements of bone fragments with inclined fracture planes. Stryker further teaches that additional teeth are preferred. The modification of Stryker suggested by the Examiner would render Stryker entirely unsatisfactory for its intended purpose because it could not hold two bone pieces together with a single point.

It is the Examiner's burden to establish prima facie obviousness. *See In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). Obviousness requires that all of the ele-

ments of a claim be known in the prior art and "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). A prima facie case of obviousness may be rebutted by showing that the art, in any material respect, teaches away from the claimed invention. *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997). A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

It is well settled that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP 2143.01; *In re Gordon*, 733 F.2d 900, 221 USPQ2d 1125 (Fed. Cir. 1984). In other words "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." MPEP 2143.01 *citing In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." MPEP 2143.01 *citing KSR*, 550 U.S. at ___, *quoting In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

The Applicants submit that the present invention is not obvious because Stryker and Clark teach away from the combination suggested by the Examiner, and the proposed combination would change the principle of operation of Stryker and Clark, in fact render either device inoperable.

Stryker is an assembly used to insert a rigid shaft into a fractured bone. The basic construction of the Stryker device is known from U.S. Patent 3,867,932 to Huene

("Huene"). (Stryker at page 2, para. 2.) The operation technique of these types of clamping devices can, in particular, be seen from FIGS. 5-8 of Huene. The two fractured bone pieces are held between two members of these types of devices. The two members of these devices form one surface of the clamp, while the second surface is formed by an elongated bow. For example, in reference to FIG. 1b of Stryker, the device comprises a hollow sleeve 32 and an elongated bow 14.

In reference to FIG. 2 and 9 of Huene, one can see that the two teeth 38 stand in contact with the upper surface of the bone piece 16 and are arranged diametrically opposite one another. It is an objective of Stryker to overcome some of the problems associated with prior art Huene. Namely it is an objective of Stryker to provide a clamping surface formed at the distal end of the hollow sleeve that be used to join two bones, wherein the configuration of the clamping surface can accommodate and engage with a more complicated bone surface and shape than the tool disclosed in Huene. In fact, Stryker plainly states this purpose, albeit in German, and cites the device disclosed in Huene as prior art. (Stryker FIG. 5a "Stand der Technik", i.e. prior art). In order to overcome this problem with the prior art, Stryker expressly teaches that multiple sets of teeth projecting from two or more planes of the distal end of the hollow sleeve are necessary to accommodate and engage with the more complicated shape and structures of the two bones.

In FIG. 6 of Stryker two fractured bone pieces 70 and 72 are joined together by a bone screw inserted with the aid of the Stryker device. Not shown in Fig. 6 is the elongated bow that forms the opposite, second clamping surface. As is clearly evident from FIG. 6, the Stryker device requires two sets of teeth: one plane with two teeth 38 which contact the first bone piece 70, and another pair of teeth in a different plane 38 to contact the second bone piece 72. Therefore, Stryker teaches that, at an absolute minimum, four teeth are necessary to hold and maintain the two bone pieces in place. In the reference shown in FIG. 4c, which the Examiners relies on, there are four teeth present. Four teeth are required because Stryker is a clamp. The four teeth engage

with the two bone pieces to secure them together and to avoid a lateral deviation or lateral movements of bone fragments with inclined fracture planes.

With the above construction, function, and purpose of Stryker set forth, it is clearly evident that a person having ordinary skill in the art would never reduce the number of teeth to a single point projecting distally, let alone reduce the number of teeth to less than four. It would render Stryker inoperable for its intended purpose because a single tip cannot hold two bones.

Clark, on the other hand, in completely unrelated to Stryker in function, structure, and medical field. As discussed in previous Amendments, Clark discloses a hollow needle which is inserted into two parts of a meniscal tissue. Meniscal tissue is not bone, but rather soft tissue. The Clark device is not a clamp, but rather a hollow needle. As can be seen from FIGS. 10A through 10F of Clark the needle is inserted through the meniscus as shown from the position from Fig. 10A to Fig 10B. The single point of Clark allows the surgeon to insert the hollow needle into the meniscus tissue. It is clear, that a second or additional tips would prevent penetration, create additional tissue damage, and render Clark inoperable for its intended purpose. Therefore, the basic idea of the construction of Clark is to provide a tip without having shoulders or other such features that would impede penetration of the needle. Therefore Clark teaches away from Stryker, in fact Clark teaches the exact opposite.

The device disclosed in the present application can neither be used as a bone clamp, or a needle. The present invention is used to attach a tendon 50 which is released from a bone 52 via an anchor. Since this device is typically used on a shoulder, the surgeon can see the bone of the shoulder lying under the tendon. The purpose of the inventive device is to assist a surgeon in targeting the place at which the anchor should be driven through the tendon and in the bone of the shoulder. Unlike, Stryker, the present invention is not a clamp for securing two bones together.

The present invention is not obvious because the Examiner has not articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. In fact, the cited references teach away from each other—Clark teaches no more than a single point, while Stryker teaches no less than four points, and preferably more. Moreover, the references have completely different function from each other and the claimed invention. Moreover, a person of ordinary skill of the art trying to overcome the disadvantage of the prior art would not look to either Stryker or Clark, as they are completely different types of devices used for completely different purposes. Finally the modification of Stryker suggested by the Examiner would render Stryker inoperable because it could not contact both bones with a single point.

Conclusion

For the foregoing reasons, the Applicants respectfully submit that all pending claims are allowable over the references of record, and earnestly solicit allowance of the same.

Respectfully submitted,

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